

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Part 573**

[Docket No. FDA-2008-F-0151] (formerly Docket No. 2007F-0478)

**Food Additives Permitted in Feed and Drinking Water of Animals; Ammonium Formate**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the regulations for food additives permitted in feed and drinking water of animals to provide for the safe use of ammonium formate as an acidifying agent in swine feed. This action is in response to a food additive petition filed by Kemira Oyj of Finland.

**DATES:** This rule is effective July 19, 2010. Submit either electronic or written objections and requests for a hearing by August 18, 2010. See section V of this document for information on the filing of objections.

**ADDRESSES:** You may submit either electronic or written objections and a request for a hearing, identified by Docket No. FDA-2008-F-0151, by any of the following methods:

*Electronic Submissions*

Submit electronic objections in the following ways:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

*Written Submissions*

Submit written objections in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

*Instructions:* All submissions received must include the agency name and docket number for this rulemaking. All objections received will be posted without change to <http://www.regulations.gov>, including any personal information provided. For detailed information on submitting objections, see the "Objections" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* For access to the docket to read background documents or objections received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the

heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

Isabel W. Pocurull, Center for Veterinary Medicine (HFV-226), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6853, e-mail: [isabel.pocurull@fda.hhs.gov](mailto:isabel.pocurull@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In a notice published in the **Federal Register** of January 11, 2008 (73 FR 2055), FDA announced that a food additive petition (animal use) (FAP 2258) had been filed by Kemira Oyj, Porkkalantatu 3, PO Box 330, 001000 Helsinki, Finland. The petition proposed to amend the food additive regulations to provide for the safe use of partially ammoniated formic acid as an acidifying agent at levels not to exceed 1.2 percent in swine feed. Subsequently, it was determined that the food additive is more accurately described as ammonium formate. The notice of filing provided for a 60-day comment period on the petitioner's environmental assessment. No comments have been received.

**II. Conclusion**

FDA concludes that the data establish the safety and utility of ammonium formate for use as proposed with modification and that the food additive regulations should be amended as set forth in this document.

**III. Public Disclosure**

In accordance with § 571.1(h) (21 CFR 571.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Veterinary Medicine by appointment with the information contact person (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 571.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

**IV. Environmental Impact**

The agency has determined under 21 CFR 25.32(r) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment, nor an environmental impact statement is required.

**V. Objections**

Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (see **ADDRESSES**) either electronic or written objections. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. It is only necessary to send one set of documents. It is no longer necessary to send three copies of all documents. Identify documents with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**List of Subjects in 21 CFR Part 573**

Animal feeds, Food additives.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 573 is amended as follows:

**PART 573—FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS**

- 1. The authority citation for 21 CFR part 573 continues to read as follows:

*Authority:* 21 U.S.C. 321, 342, 348.

- 2. Add § 573.170 to read as follows:

**§ 573.170 Ammonium formate.**

The food additive, partially ammonium formate, may be safely used in the manufacture of complete swine feeds in accordance with the following prescribed conditions:

(a) The additive is manufactured by the reaction of 99.5 percent ammonia gas and 99 percent formic acid in a continuous loop reactor to produce a solution made up of 37 percent ammonium salt of formic acid and 62 percent formic acid.

(b) The additive is used or intended for use as a feed acidifying agent, to lower the pH, in complete swine feeds at levels not to exceed 1.2 percent of the complete feed.

(c) To assure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act (the act), the label and labeling shall contain:

(1) The name of the additive.

(2) Adequate directions for use including a statement that ammonium formate must be uniformly applied and thoroughly mixed into complete swine feeds and that the complete swine feeds so treated shall be labeled as containing ammonium formate.

(d) To assure safe use of the additive, in addition to the other information required by the act and paragraph (c) of this section, the label and labeling shall contain:

(1) Appropriate warnings and safety precautions concerning ammonium formate (37 percent ammonium salt of formic acid and 62 percent formic acid).

(2) Statements identifying ammonium formate in formic acid (37 percent ammonium salt of formic acid and 62 percent formic acid) as a corrosive and possible severe irritant.

(3) Information about emergency aid in case of accidental exposure as follows:

(i) Statements reflecting requirements of applicable sections of the Superfund Amendments and Reauthorization Act (SARA), and the Occupational Safety and Health Administration's (OSHA) human safety guidance regulations.

(ii) Contact address and telephone number for reporting adverse reactions or to request a copy of the Material Safety Data Sheet (MSDS).

Dated: July 14, 2010.

**Tracey H. Forfa,**

*Acting Director, Center for Veterinary Medicine.*

[FR Doc. 2010-17565 Filed 7-16-10; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Part 54

[TD 9493]

RIN 1545-BJ60

## DEPARTMENT OF LABOR

### Employee Benefits Security Administration

#### 29 CFR Part 2590

RIN 1210-AB44

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

[OCIO-9992-IFC]

#### 45 CFR Part 147

RIN 0938-AQ07

### Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act

**AGENCIES:** Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Office of Consumer Information and Insurance Oversight, Department of Health and Human Services.

**ACTION:** Interim final rules with request for comments.

**SUMMARY:** This document contains interim final regulations implementing the rules for group health plans and health insurance coverage in the group and individual markets under provisions of the Patient Protection and Affordable Care Act regarding preventive health services.

**DATES:** *Effective date.* These interim final regulations are effective on September 17, 2010.

*Comment date.* Comments are due on or before September 17, 2010.

*Applicability dates.* These interim final regulations generally apply to group health plans and group health insurance issuers for plan years beginning on or after September 23, 2010. These interim final regulations generally apply to individual health insurance issuers for policy years beginning on or after September 23, 2010.

**ADDRESSES:** Written comments may be submitted to any of the addresses specified below. Any comment that is submitted to any Department will be

shared with the other Departments. Please do not submit duplicates.

All comments will be made available to the public. **WARNING:** Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments are posted on the Internet exactly as received, and can be retrieved by most Internet search engines. No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously.

*Department of Labor.* Comments to the Department of Labor, identified by RIN 1210-AB44, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *E-mail:* [E-OHPSCA2713.EBSA@dol.gov](mailto:E-OHPSCA2713.EBSA@dol.gov).

- *Mail or Hand Delivery:* Office of Health Plan Standards and Compliance Assistance, Employee Benefits Security Administration, Room N-5653, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, *Attention:* RIN 1210-AB44.

Comments received by the Department of Labor will be posted without change to <http://www.regulations.gov> and <http://www.dol.gov/ebsa>, and available for public inspection at the Public Disclosure Room, N-1513, Employee Benefits Security Administration, 200 Constitution Avenue, NW., Washington, DC 20210.

*Department of Health and Human Services.* In commenting, please refer to file code OCIO-9992-IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the instructions under the "More Search Options" tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, Attention: OCIO-9992-IFC, P.O. Box 8016, Baltimore, MD 21244-1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the